REMARKS

In response to the Examiner's objections to the specification due to informalities, the specification has been amended. Specifically, paragraph 73 on page 28 has been deleted and paragraph 264 on page 98 has been replaced. The table spanning pages 39-40 to show amino acid codes, which are well known in the art as of the priority date of this application, is deleted. The rest of tables in the specification have been and are currently numbered and the Examiner is invited to confirm that this is the case. Applicants request reconsideration and withdrawal of the objection to the labeling of the tables in the specification.

The amendments correct typographical and clerical errors in the specification and no new matter is included.

Claims 1-3, 9 and 16 are pending in the present application. The Examiner rejects claims 1-3, 9 and 16 under 35 U.S.C. 112, second paragraph, as being vague and indefinite because of the recitation of "at least one." Applicants respectfully disagree. However, in the interest of expediting prosecution of the present application, claims 1, 9 and 16 have been amended such that the amended claims do not include the phrase "at least one." Reconsideration and withdrawal of the rejection of claims 1-3, 9 and 16 under 35 U.S.C. 112, second paragraph, are respectfully requested.

The Examiner rejects claim 3 under 35 U.S.C. 112, second paragraph, as being vague and indefinite for claiming, "neutralizes at least one activity of at least one TNF protein." Applicants respectfully disagree. However, in the interest of expediting prosecution of the present application, claim 3 has been amended to recite a TNF antibody according to claim 1, wherein said antibody is a neutralizing antibody. The support for this amendment can be found in paragraph 102, lines 13-24, on page 36 of the present specification. Reconsideration and withdrawal of the rejection of claim 3 under 35 U.S.C. 112, second paragraph, are respectfully requested.

The Examiner rejects claims 1, 9 and 16 under 35 U.S.C. 112, first paragraph, as not providing enablement for mammalian anti-TNF antibodies comprising at least SEQ ID NO:

7 and SEQ ID NO: 8 as a variable region. Applicants respectfully disagree. However, in the interest of expediting prosecution of the present application, the claims have been amended to recite human anti-TNF antibodies. As the examiner stated in section 7a on page 3 of the last office action (mailed on 6/28/2005), the present application is enabling for human anti-TNF antibody comprising a heavy or light variable region of SEQ ID NO: 7 and 8. Reconsideration and withdrawal of the rejection of claims 1, 9 and 16 under 35 U.S.C. 112, first paragraph, are respectfully requested.

The Examiner also rejects claim 16 under 35 U.S.C. 112, first paragraph, as not providing enablement for the administration or contacting human anti-TNF antibody by parenteral, subcutaneous, intramuscular, intravenous, intrarticular, intrabronchial, intraabdominal, intracapsular, intracartilaginous, intracavitary, intracelial, intracelebellar, intracerebroventricular, intracolic, intracervical, intragastric, intrahepatic, intramyocardial, intraosteal, intrapelvic, intrapericardiac, intraperitoneal, intrapleural, intraprostatic, intrapulmonary, intrarectal, intrarenal, intraretinal, intraspinal, intrasynovial, intrathoracic, intrauterine, intravesical, bolus, vaginal, rectal, buccal, sublingual, intranasal, or transdermal means. Applicants respectfully disagree. However, in the interest of expediting prosecution of the present application, the claims have been amended to recite the administration or contacting human anti-TNF antibody by parenteral, subcutaneous, intramuscular, and intravenous means.

In this matter, applicants respectfully direct the examiner's attention to paragraphs 174 and 178, where parenteral formulations and administration have been described in detail. It is well known that parenteral is defined as "not through the alimentary canal but rather by injection throughsome other route, as subcutaneous, intramuscular, intraorbital, intracapsular, intraspinal, intrasternal, intravenous, etc." Dorland's Illustrated Medical Dictionary 1231 (27th ed., Saunders 1988). In addition, the specification has specifically pointed out that parenteral administration includes means such as subcutaneous, intramuscular or intravenous. Paragraph 179, lines 13-14, page 69.

The specification in a patent application does not need to disclose what is well known in the art in order to meet the enablement requirement. Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366 (Fed. Cir. 1997). The procedures of administration through parenteral, subcutaneous, intramuscular, and intravenous means are well known in the art. See, The Merck Manual (12^{th} –17^{th} Eds) and Pharmacotherapy Handbook (2^{nd} Ed), each has been entirely incorporated by reference. Therefore, the amended claim 16 is fully enabled. Reconsideration and withdrawal of the rejection of claim 16 under 35 U.S.C. 112, first paragraph, are respectfully requested.

SUMMARY

In view of the foregoing remarks, reconsideration and withdrawal of the rejections and allowance of all pending claims are respectfully requested.

Cancellation of and/or amendments to the claims should in no way be construed as acquiescence to any of the Examiner's objections and/or rejections. They are being made solely to expedite prosecution of the present application and are not related to any issues of patentability. Applicants reserve the option to further prosecute the same or similar claims in the present or another patent application.

This response is timely filed within the 3-month shortened statutory period for reply. However, if any fees are due in connection with the filing of this response, authorization is hereby given to charge the amount of such fee to Deposit Account No. 10-0750/CEN0250NP/GKT in the name of Johnson & Johnson.

Respectfully submitted,

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